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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,751	11/10/2003	Cameron Rouns	BAL-115-CIP (16301.1)	4276
22827	7590	11/29/2005	EXAMINER	
DORITY & MANNING, P.A. POST OFFICE BOX 1449 GREENVILLE, SC 29602-1449			ZACHARIA, RAMSEY E	
			ART UNIT	PAPER NUMBER
			1773	
DATE MAILED: 11/29/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/705,751

Applicant(s)

ROUNS ET AL

Examiner

Ramsey Zacharia

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 1-22 and 37-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/16/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I in the reply filed on 02 November 2005 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-22 and 37-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 02 November 2005.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: **10** (aspirating device). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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Claim Objections

4. Claim 35 is objected to because of the following informalities: the term "Dimethylanimoethyl" on line 2 of the claim should be --Dimethylaminoethyl--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 26 is rendered indefinite because the structure recited in the claim is that of a quaternary amine acrylate monomer and not a quaternary amine acrylate polymer.

Claim Language

8. For the purpose of examination, the structure recited in claim 26 is taken to be the monomer from which the quaternary amine acrylate polymer is formed.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 23, 24, 26, 27, and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michal et al. (U.S. Patent 6,287,285).

Michal et al. is directed to a coating provided on the surface of a medical device, such as a catheter or guidewire (column 2, lines 5-12). The coating may comprise a hydrated layer formed by applying a solution containing a hydrophilic polymer and a grafting component which crosslinks the hydrophilic polymer (column 5, lines 9-17). The grafting component adheres to the surface of the device, that is, it is imbibed into the surface according to the definition for the term "imbibing" presented on page 4, lines 31-32 of the instant specification (column 2, lines 19-20). Suitable grafting components include allyl compounds and acrylate compounds, such as trimethylol propane triacrylate or pentaerythritol tetraacrylate (column 6, lines 60-64). The coating may be applied to any device having a polymeric surface, such as a catheter formed from high density polyethylene or nylon (which are thermoplastics) (column 5, lines 34-42). Michal et al. also teach a polymer of an amino acrylate, such as 2-aminoethyl acrylate, as a hydrophilic material (column 7, lines 66-column 8, line 10).

It would be obvious to one skilled in the art to use the polymer of 2-aminoethyl acrylate as the hydrophilic polymer of the coating since the polymer of 2-aminoethyl acrylate is taught to be a hydrophilic polymer. Upon hydration of the coating layer, a polymer of 2-aminoethyl acrylate would comprise some units of the structure as recited in claim 26, wherein $X = O$, $n = 2$, $R' = R'' = R''' = H$, and $Y = OH$, particularly when the device contacts an acid environment (e.g. stomach acids, etc.).

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Regarding claim 35, since Michal et al. explicitly teach the use of allyl and acrylate compounds as the grafting component, it would be within the ability of one skilled in the art to select the appropriate allyl or acrylate compound.

11. Claims 25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michal et al. (U.S. Patent 6,287,285) in view of Kousai et al. (EP 191,471).

Michal et al. teach all the limitations of claims 25 and 28, as outlined above, except for the use of polyvinyl chloride, silicone, or polyurethane as the polymer of the medical device. However, Michal et al. do explicitly teach that their coating may be applied to any device having a polymeric surface and cite a catheter formed of conventional materials as an example (column 5, lines 34-36).

Kousai et al. teach a catheter formed from a synthetic resin (abstract). The synthetic resin may be a vinyl chloride resin (e.g. PVC), polyurethane, polyethylene, or silicone resins (page 4, lines 27-30).

Kousai et al. illustrate that in addition to polyethylene, catheters are also conventionally formed from polyvinyl chloride, polyurethane, and silicone resins. Kousai et al. show that polyvinyl chloride, polyurethane, silicone, and polyethylene are known in the art as functionally equivalent materials for forming catheters. Therefore, because these polymers were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute polyvinyl chloride, polyurethane, or silicone for the polyethylene in the catheter of Michal et al.

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12. Claims 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michal et al. (U.S. Patent 6,287,285) in view of Perrault et al. (U.S. Patent 6,039,940).

Michal et al. teach all the limitations of claims 29 and 30, as outlined above, except for reciting the particular acrylate polymers. However, Michal et al. do teach that a polymer formed from a hydrophilic agent such as 2-aminoethyl acrylate that is used (in conjunction with a grafting agent) to form a hydrogel coating.

Perrault et al. disclose that polymers formed from monomers of FORMULA I in column 3 may be used to form hydrogels used in medical applications.

That is, Perrault et al. teach the functional equivalence of any monomer that meets the requirement of FORMULA I, which includes 2-aminoethyl acrylate (for the reasons outlined above) as well as the monomers recited in instant claims 29 and 30. Therefore, because these monomers were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to use any monomer of FORMULA I in place of the 2-aminoethyl acrylate monomer taught by Michal et al.

13. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Michal et al. (U.S. Patent 6,287,285) in view of Wu et al. (U.S. Patent 6,083,393).

Michal et al. teach all the limitations of claim 36, as outlined above, except for the use of ethoxylated trimethylolpropane triacrylate as the grafting component. However, Michal et al. do teach the use of acrylate compounds in general as their grafting component and cite pentaerythritol tetraacrylate as a specific example.

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Wu et al. teach that acrylates such as pentaerythritol tetraacrylate and ethoxylated trimethylolpropane triacrylate may be used to crosslink hydrophilic polymers (column 3, line 56-column 4, line 12).

That is, Wu et al. shows that pentaerythritol tetraacrylate and ethoxylated trimethylolpropane triacrylate are known in the art as functionally equivalent acrylates for crosslinking hydrophilic polymers. Therefore, because these two acrylates were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute ethoxylated trimethylolpropane triacrylate for pentaerythritol tetraacrylate.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 23-36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-26 of copending Application No.

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10/325,443. Although the conflicting claims are not identical, they are not patentably distinct from each other because the inventions of instant claims 23-36 represent a genus of which the inventions described by claims 18-26 of copending Application No. 10/325,443 are species. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993). The instant claims require the multi-functional monomer to comprise an acrylate or ammonium compound, while copending Application No. 10/325,443 claims specific acrylates and ammonium compounds as the multi-functional monomer. These specific acrylates and ammonium compounds represent species of the genus recited in instant claim 23.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ramsey Zacharia whose telephone number is (571) 272-1518. The examiner can normally be reached on Monday through Friday from 9 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney, can be reached at (571) 272-1284. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ramsey Zacharia
Primary Examiner
Tech Center 1700